K081372

FEB - 4 2009

510(k) Summary

Date: December 10, 2008

1. Submission Applicant & Correspondent:

Name:	BMG Pharma LLC
Address:	824 Highway 88 Gardnerville, NV 89460 USA
Phone:	(775) 265-6529
Mobile:	(714) 743-9302
Contact Person:	Dr. Gary Pekoe President & CEO Arkios BioDevelopment International 421 S Lynnhaven Rd, Suite 101 Virginia Beach, VA 23451 USA
Phone:	(757) 631-2114
Fax:	(757) 631-2115

2. Name of Device: **GelX® ORAL GEL**
Trade Name: **GelX® ORAL GEL**
Common Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic
Classification Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

3. Devices to which new device is Substantially Equivalent:
Sinclair Pharmaceuticals, Ltd., Gelclair® Concentrated Oral Gel (K013056)

4. Device Description:
BMG Pharma's **GelX® ORAL GEL** is a viscous gel formulation, which is presented in both 300 ml and 450 ml bottles. This combination of substances, when washed around the mouth, forms a protective layer over the oral mucosa.

5. Intended Use of the Device:
BMG Pharma's **GelX® ORAL GEL** has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, and traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated for diffuse aphthous ulcers.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:
BMG Pharma's **GelX® ORAL GEL** has the same intended/indications for use as the predicate Sinclair Pharmaceuticals, Ltd., Gelclair® Concentrated Oral Gel (K013056).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2009

Mr. William A. Goolsbee
BMG Pharma LLC.
824 Highway 88
Gardnerville, Nevada 89460

Re: K081372
Trade/Device Name: GelX® ORAL GEL
Regulation Number: None
Regulation Name: Unclassified
Regulatory Class: None
Product Code: MGQ
Dated: December 31, 2008
Received: January 2, 2009

Dear Mr. Goolsbee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081372

Indications for Use

510(k) Number (if known): K081372

Device Name: **GelX® ORAL GEL**

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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